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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,070	07/30/2003	David R. Milich	VACCINE-07083	9382

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EXAMINER	
MCGAW, MICHAEL M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,070	MILICH ET AL.	
	Examiner	Art Unit	
	Michael M. McGaw	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20, drawn to chimeric woodchuck hepatitis virus core polypeptide of SEQ ID NO: 38 with a heterologous polypeptide attached thereto, classified in class 530, subclass 350.

II. Claims 21- 24, drawn to a method of inducing an immune response using woodchuck hepatitis virus core antigen of SEQ ID NO: 38 linked to a heterologous antigen, classified in class 424, subclass 189.1.

III. Claims 25-31, drawn to a method of producing an immunogenic composition using a hepatitis virus core antigen, classified in class 424, subclass 189.1.

IV. Claim 32-33, drawn to a chimeric hepatitis virus core antigen of SEQ ID NO: 40 with or without a heterologous polypeptide attached thereto, classified in class 530, subclass 350.

V. Claim 34, drawn to a method of inducing an immune response using core antigen of SEQ ID NO: 40 linked to a heterologous antigen, classified in class 424, subclass 189.1.

VI. Claim 35, drawn to a method of producing an immunogenic composition using a ground squirrel hepatitis virus core antigen, classified in class 424, subclass 189.1.

The inventions are distinct, each from the other because of the following reasons:

The following is a quotation from MPEP 803.01:

> There are two criteria for a proper requirement for restriction between patentably distinct inventions:
>
> (A) The inventions must be **independent** (see MPEP § 802.01, § 806.04, § 808.01) ***or*** **distinct** as claimed (see MPEP § 806.05 - § 806.05(i)); and
>
> (B) There must be a **serious burden** on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02). (emphasis added)

Additionally:

> For purposes of the initial requirement, a **serious burden** on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02.

The inventions of I-II are unrelated to the inventions of IV-VI. The inventions of I-II all require SEQ ID NO: 38. The inventions of IV-VI do not require SEQ ID NO:38. The inventions of IV-V all require SEQ ID NO: 40, while Invention VI requires GSHc (Ground Squirrel hepatitis core). The inventions of I-II do not require SEQ ID NO:40 or GSHc. Thus, these inventions are independent from one another. The claims do not indicate the inventions are usable together. Furthermore, SEQ ID NO: 38 (a WHc sequence) is a structurally distinct chemical compound from SEQ ID NO:40 (a GSHc sequence). Thus, Inventions I-II are also distinct from Inventions IV-VI.

Inventions I-II relate to WHc (Woodchuck Hepatitis virus core) sequence while Inventions IV-VI relate to GSHc. Thus, it is apparent by the nomenclature that these have achieved a separate status in the art. Furthermore, the search for WHc in the literature search would not be expected to be coextensive with the search for GSHc.

Therefore, examination of Inventions I-II with Inventions IV-VI would impose serious burden.

Invention I is distinct from Inventions II-III, and each distinct from the other. Invention I relates to a protein. Invention II relates to a method of inducing an immune response. Invention III relates to a method of producing an immunogenic composition.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The recombinant antigens of Invention I could be used in an ELISA to screen for antibody reactive with the core molecule or for affinity purification of antibodies to the core molecule. Inventions I and II are therefore distinct.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process claimed in invention III could be practiced with a human HBc core antigen. The recombinant antigens of Invention I could be used in an ELISA to screen for antibody reactive with the core molecule or for affinity purification of antibodies to the core molecule. Inventions I and III are therefore distinct.

Searching the inventions of Inventions I through III would impose a serious burden. Invention I has a separate status from Inventions II and III as shown by their different classification. The field of search for the immunogenic composition of Invention I is not coextensive with the search for a method of producing an immunogenic composition using any hepatitis virus core antigen as in Invention III as the search for Invention I relates only to WHc while the search for Invention relates to any core antigen. The search for Invention I is not coextensive with the method of inducing an immune response with the product of Invention I as the product could be used in other methods such as diagnostic tests. Therefore, examination of Inventions I-III together would impose serious burden.

Invention IV is distinct from Inventions III and V-VI and each is distinct from the other

Inventions III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process claimed in invention III could be practiced with a human HBc core antigen rather than the SEQ ID NO:40 (GSHc). Additionally, the antigens of Invention IV could be used in an ELISA to screen for antibody reactive with the core molecule or for affinity purification of antibodies to the core molecule. Inventions III and IV are therefore distinct.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method claimed in invention V could be practiced with a human HBc core antigen other than SEQ ID NO: 38. The antigens of Invention III could be used in an ELISA to screen for antibody reactive with the particular epitope inserted. Inventions IV and V are therefore distinct.

Inventions IV and VI are related as product made and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process claimed in invention VI could be practiced with a GSHc core antigen with a sequence other than SEQ ID NO:40. Inventions I and IV are therefore distinct.

Searching the inventions of Inventions III through VI would impose a serious burden. The search for Invention V is not coextensive with the method of inducing an immune response with the fusion chimera as in claim VII as the fusion chimera product of Invention V could be used in other methods such as diagnostic tests to detect antibody to the antigen. The search for the fusion chimera of Invention IV is not coextensive with the search for the immunogenic composition of Invention VI as the

immunogenic composition of Invention VIII utilizes any GSHc sequence while the fusion chimera of Invention V requires SEQ ID NO: 40. Invention IV has attained a different status in the art as evidenced by their separate classification from inventions III and V-VI. Therefore, examination of Inventions III-VI together would impose serious burden.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Species election:

If applicant elects Group I, applicant **must further elect a species** for examination. Claim 1 of group I is related to the generic use of SEQ ID NO: 38 of WHc as a carrier for antigens comprising B cell and/or T cell epitopes. ***Numerous*** species exist within this generic claim. Applicant must elect a particular species for examination. If applicant elects the species on the basis of the insert site applicant should specify:

(1) the particular insert site (**or** must elect a conjugated antigen).

(2) the peptide fused to the C-terminal from those listed in claims 13-15 or identify the sequence as ending at residue 149. Note that claims 13-15 contain

49 different peptides as represented by their SEQ ID NOs as well as 5 additional terminal sequences.

In making the election, applicant should particularly identify the species elected and point out the claims corresponding to the elected species.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael M. McGaw whose telephone number is (571) 272-2902. The examiner can normally be reached on Monday through Friday from 8 A.M. to 5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. McKelvey

Saturday, September 18, 2004

MARY E. MOSHER
PRIMARY EXAMINER
GROUP ~~1800~~ 1600